

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT:	ROZIER <i>et al.</i>	)	ATTORNEY DOCKET:	04308057
		)		
SERIAL NO.:	10/501,604	)	GROUP ART UNIT:	3772
		)		
FILING DATE:	October 28, 2004	)	EXAMINER:	JACKSON, Brandon Lee
		)		
TITLE:	SITE GUARD FOR INTRAVENOUS SITES AND OTHER SENSITIVE AREAS			
		)		
DATE:	October 25, 2010	)	CUSTOMER NO.:	26565
		)		

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL DECLARATION OF LISA M. VALLINO UNDER 37 C.F.R. § 1.131**

I, Lisa M. Vallino, declare and state as follows:

1. I am one of the inventors of the subject matter provided in the above-captioned patent application, and one of the co-founders of I.V. House, Inc., which is the assignee of the above-captioned application. I have personal knowledge of the facts stated herein.
2. The above-captioned patent application discloses and claims, among other things, a site guard for intravenous sites and other sensitive areas that fastens to a patient without having to place adhesive tape on the skin of the patient.
3. I have reviewed the Shesol patent, U.S. Patent No. 6,257,240 having a filing date of June 5, 2000.
4. I submit this declaration to supplement the information I provided to the Patent Office in my November 12, 2008 and September 14, 2009 declarations.

5. In 1991, I conceived of a site guard having the shape of a U-Shaped domed cup to protect intravenous sites and other sensitive areas (“I.V. House Site Guard”). This product is covered by the claims of U.S. Patent No. 5,167,240 (the “’240 Patent”).

6. On January 28, 1991, Betty Rozier (“Ms. Rozier”), my mother and co-founder of I.V. House, Inc. and I filed a design patent application titled “SHIELD FOR I.V. SITES” for one embodiment of an I.V. House Site Guard. This design application issued as U.S. Patent No. D335,926 (the “’926 Patent”). The figures of the ’926 Patent disclose a site guard comprising a hollow member having a U-shaped base, the base having an edge to be positioned upon a patient adjacent a site, the base having a width sufficient to straddle the site and a length and a height sufficient to cover the site, the base joined to a sidewall to form a cover. The site guard of the ’926 Patent also discloses a flange attached to the lower edge of the hollow member. *See* U.S. Pat. No. D335,926 at Figs. 1-6. A copy of the ’926 Patent is attached hereto as Exhibit A.

7. As early as 1993, Ms. Rozier and I exhibited the I.V. House Site Guard product at various conferences, during which time we received interest in our product from nurses who work exclusively with geriatric patients. We became concerned that the use of an I.V. House Site Guard that is secured with adhesive tape would not be beneficial to geriatric patients due to the harm that the adhesive tape can cause to their fragile skin. Because of such interest from the nurses, and the problem we had identified, we determined we needed to develop a similar site guard that could be secured to a patient without the use of any adhesive tape.

8. Between 1993 and 1999, Ms. Rozier and I conceived of new variations for the I.V. House Site Guard, including a site guard that could be secured to a patient without the use of any adhesives on a patient’s skin. One embodiment utilized the site guard disclosed in the ’926

Patent and included a fabric connector affixed to the flange thereof such that it does not traverse the sidewall of the site guard.

9. During this same time period, we at all times continuously and diligently worked to achieve actual reduction to practice of our inventive concept for an adhesive-free site guard by, among other efforts, experimenting with various designs, techniques, concept prototypes, and materials so as to achieve an actual working product having all the properties required of our inventive concept.

10. At least as of January 8, 2000, following several years of continuous and diligent efforts to achieve actual reduction to practice of our inventive concept, we created several hand-drawn sheets of drawings detailing the various design embodiments of our inventive concept. Each of the dated, hand-drawn, drawings is attached hereto as Exhibit B. While the drawings are somewhat basic in nature, the drawings of Exhibit B were intended to depict various embodiments of a fabric connector affixed to a site guard hollow member. The hollow member depicted in each of the drawings of Exhibit B was intended to represent either the hollow member as disclosed in the '240 Patent or the hollow member as disclosed in the '926 Patent. Thus, the fabric connectors depicted in the drawings of Exhibit B are affixed at either a lower edge or flange of the site guard's hollow member, such that it does not traverse the sidewall. *See, e.g.*, Figs. 7 and 8 of Exhibit B. Ms. Rozier also created a drawing which specifically depicted the site guard disclosed in the '926 Patent and included a fabric connector affixed to the flange thereof such that the fabric connector did not traverse the sidewall of the site guard. Unfortunately, the original drawing has been lost, but an accurate reproduction of the drawing can be found at Exhibit C. Exhibit C, as labeled is a top-down plan view drawing depicting a hollow member, having a U-shaped base, that is joined to a sidewall to form a cover. At the

lower edge of the hollow member is an attached flange, to which a fabric connector (shown by crosshatching) is affixed such that it does not traverse the sidewall. An alternate, 3-D, orthographic projection view of the drawing of Exhibit C can be found at Exhibit D, which has been included to clarify the drawing of Exhibit C. As in Exhibit C, Exhibit D also depicts a hollow member, having a U-shaped base, that is joined to a sidewall to form a cover. At the lower edge of the hollow member is an attached flange, to which a fabric connector is affixed such that it does not traverse the sidewall. Accordingly, at the very latest, we achieved reduction to practice of our inventive concept on January 8, 2000, if not significantly earlier.

11. In addition, we created physical prototypes of several of the inventive embodiments that were depicted in the drawings dated January 8, 2000 as well as prototypes of embodiments that were not included in the drawings of January 8, 2000. Ms. Rozier and I created these prototypes for the purposes of physical experimentation, proof of concept, and actual reduction to practice. For example, Ms. Rozier created a prototype based on the drawing set forth at Exhibit C. Particularly, Ms. Rozier drew a site guard as disclosed in the '240 Patent on a piece of paper. She then cut up a plastic lid from a food container and made a flange to determine the appropriate width of the flange. Next, she placed the flange around the drawn site guard. Finally, she drew straight lines outward and perpendicular to the top and bottom edges of the flange, which represented the fabric connector attached only to the flange portion of the site guard. She conceived of a variation of the site guard where the entire fabric band would be as wide as from the top edge of the flange to the bottom edge of the flange. We discussed gluing and welding as means to secure the fabric connector to the flange without traversing the wall of the site guard. We also discussed sewing the fabric connector to the flange or applying a double-coated adhesive film to the flange and then removing the release paper on the opposite side of

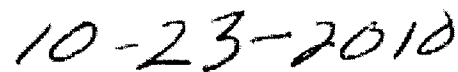
the film and align the flange with the fabric connector so that the fabric connector did not traverse the wall of the site guard.

12. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



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Lisa Vallino



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Date

# EXHIBIT A



US00D335926S

**United States Patent** [19]

Rozier et al.

[11] Patent Number: Des. 335,926

[45] Date of Patent: \*\* May 25, 1993

[54] SHIELD FOR I.V. SITES

[76] Inventors: Betty M. Rozier, 7400 Foxmont,  
Hazelwood, Mo. 63042; Lisa M.  
Vallino, 6550 Dale, St. Louis, Mo.  
63139

[\*\*] Term: 14 Years

[21] Appl. No.: 648,617

[22] Filed: Jan. 28, 1991

[52] U.S. Cl. .... D24/130

[58] Field of Search .... D24/127, 130; 128/846,  
128/877, 878, 879, DIG. 6, DIG. 26; 604/174,  
180, 192, 197, 198

[56] References Cited

## U.S. PATENT DOCUMENTS

D. 327,321	6/1992	Russell et al.	D24/130
3,194,235	7/1965	Cooke	604/180 X
3,900,026	8/1975	Wagner	128/DIG. 26 X
4,517,971	5/1985	Sorbonne	604/174 X
4,633,863	1/1987	Filips et al.	604/180 X

4,679,553	7/1987	Proulx et al.	604/174 X
4,898,587	2/1990	Mera	604/174
5,074,847	12/1991	Greenwell et al.	604/174

Primary Examiner—Stella Reid

Assistant Examiner—Ian Simmons

Attorney, Agent, or Firm—Grace J. Fishel

[57] CLAIM

The ornamental design for a shield for I.V. sites, as shown.

## DESCRIPTION

FIG. 1 is a perspective view of a shield for I.V. site showing my new design, the broken line showing of the hand, arm board and I.V. tubing is for illustrative purposes only and forms no part of the claimed design;

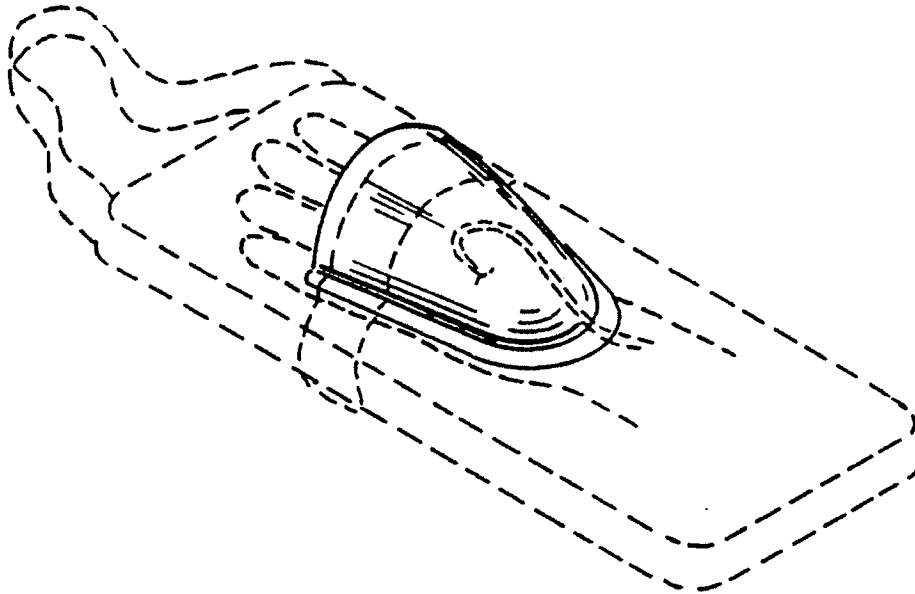
FIG. 2 is a top plan view thereof;

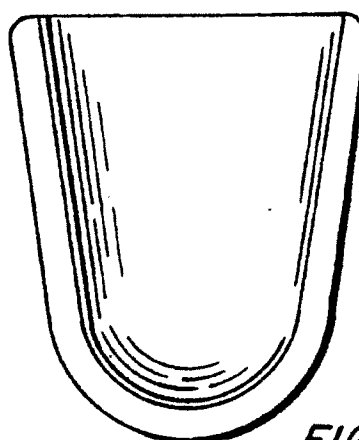
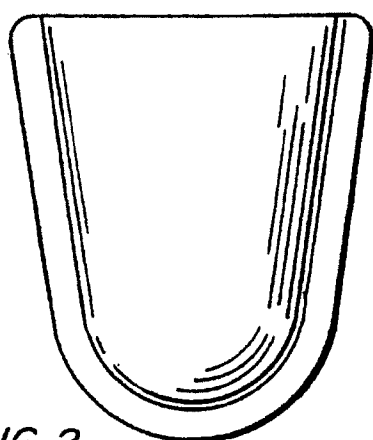
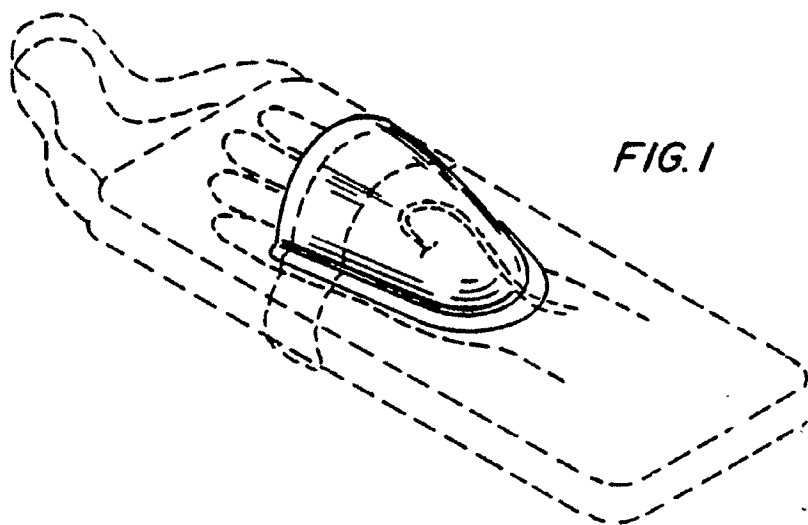
FIG. 3 is a bottom plan view thereof;

FIG. 4 is a side elevational view thereof, the opposite side elevational being identical thereto;

FIG. 5 is a front elevational view thereof; and,

FIG. 6 is a rear elevational view thereof.



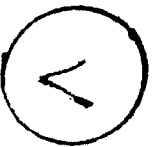


# EXHIBIT B

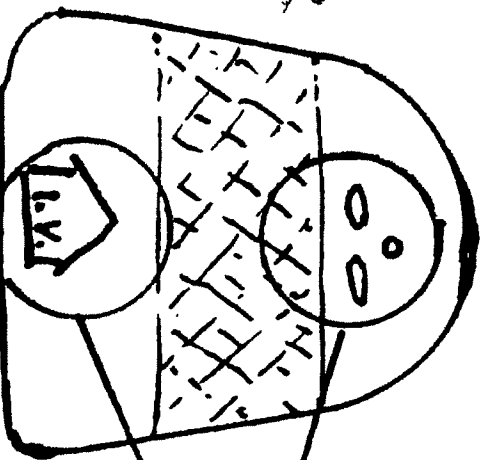
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FIG 1

DRAWINGS NOT TO SCALE  
LARGE SIZE I.V. HOUSE TACK USED



INDICATES  
VELCRO  
HOOK  
FASTENER

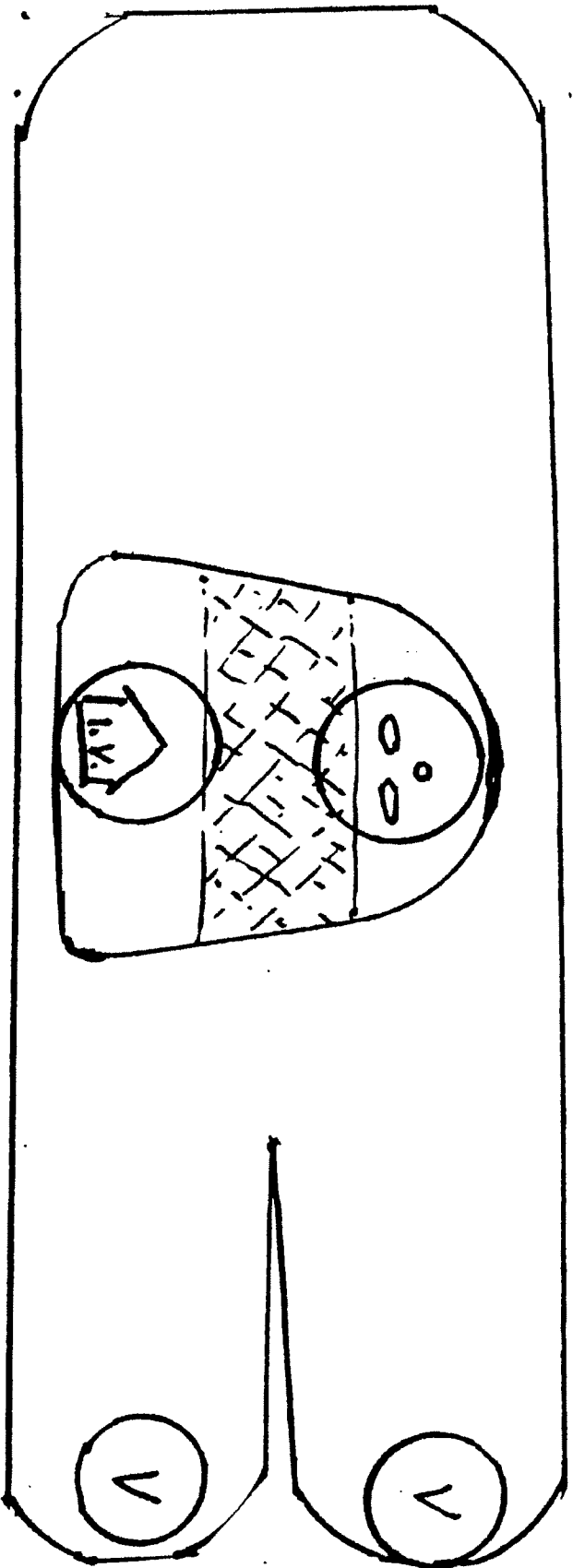


SHAVED AREAS  
INDICATE TAPELESS  
DRESSING

INDICATE 2  
CIRCULAR  
HOLES INTENDED  
FOR VENTILATION  
AND I.V. HOUSE  
AND BE VISIBLE  
WHEN TAPELESS  
DRESSING COVERS  
AN I.V. HOUSE.

1-5-10000

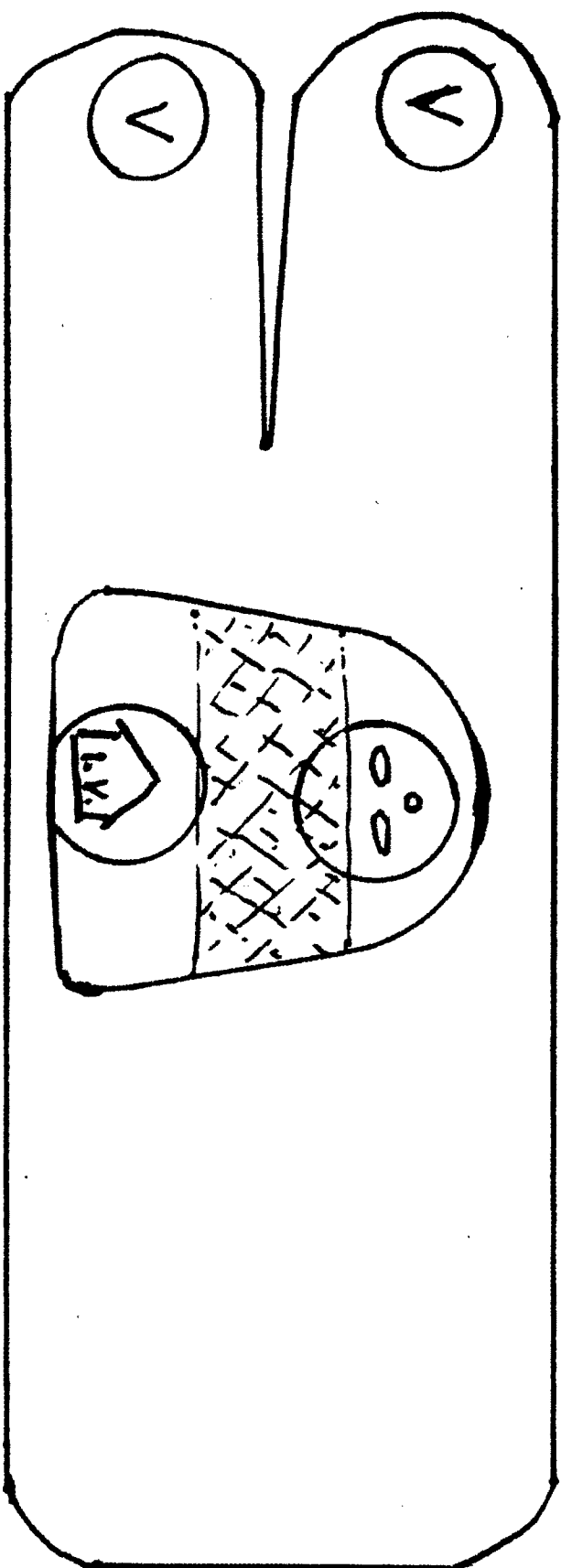
FIG. 2



RIGHT HAND

1-8. 2000

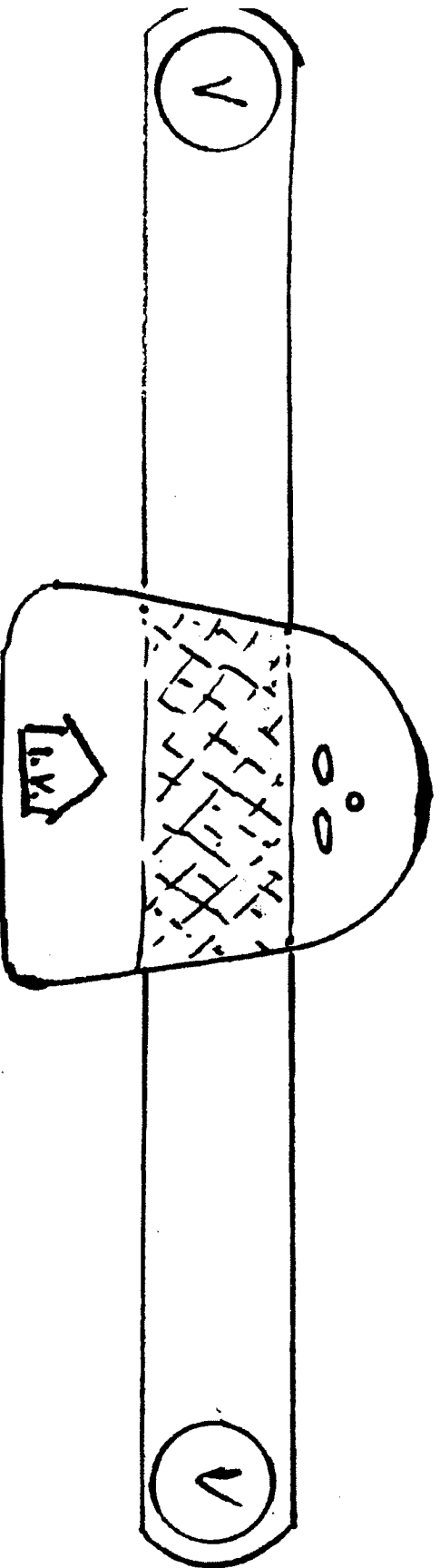
F. 4. 3



LEFT HAND

1. 8-2000

FIG. 4

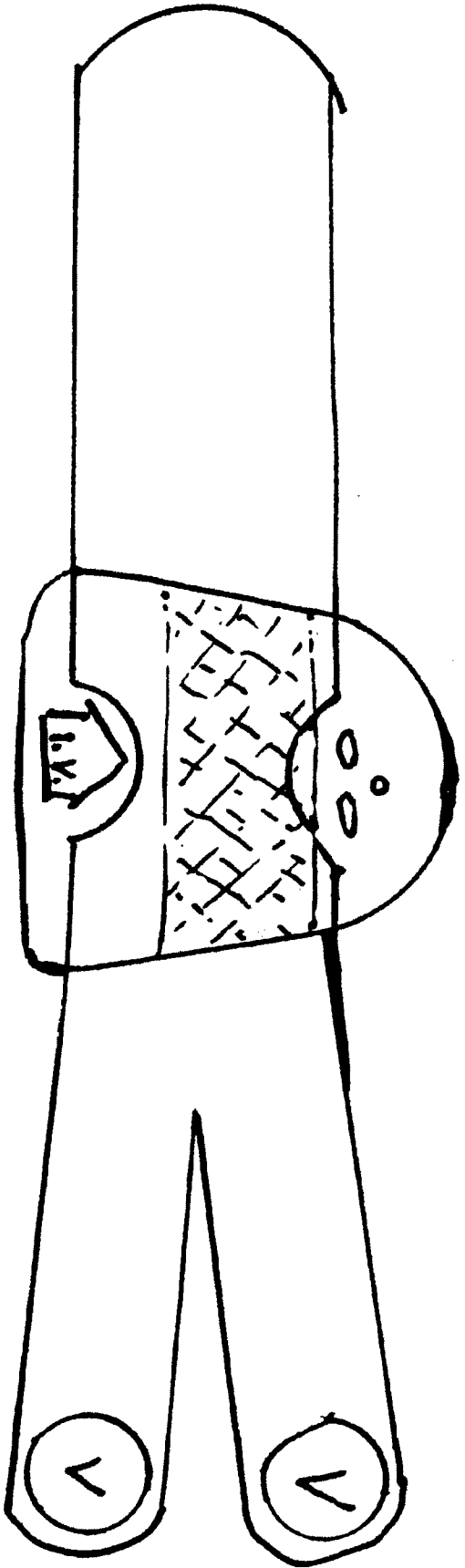


AMBIDEXTROUS HAND OR ARM

UNUSED FASTENER SIMPLY FOLDS UNDER

1-8 Dec

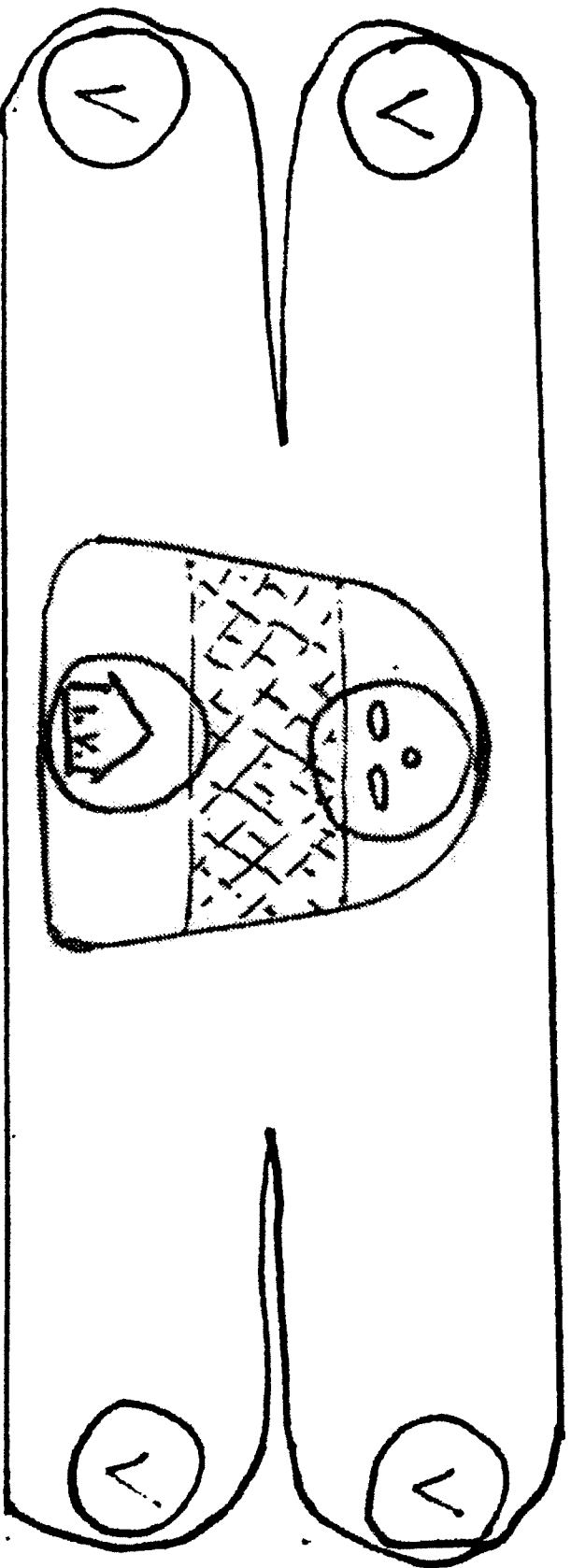
1-5.5



LEFT HAND  
REVERSE ENDS FOR RIGHT HAND

1-8-2000

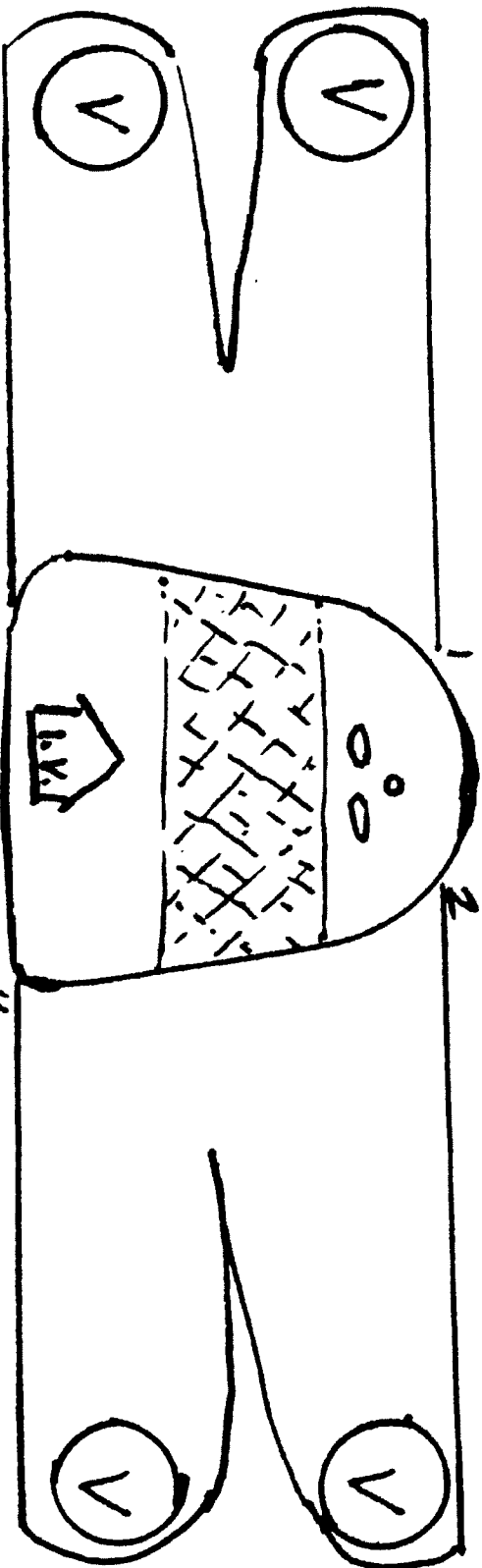
Ch. 6



AMBI DEXTROUS HAND OR ARM  
2 CIRCULAR OPENINGS EXPOSE  
VENTILATION AND LOGO

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FIG. 7



AMBI DEXTROUS HAND

OR ARM

TAPELLESS

WELDED TA

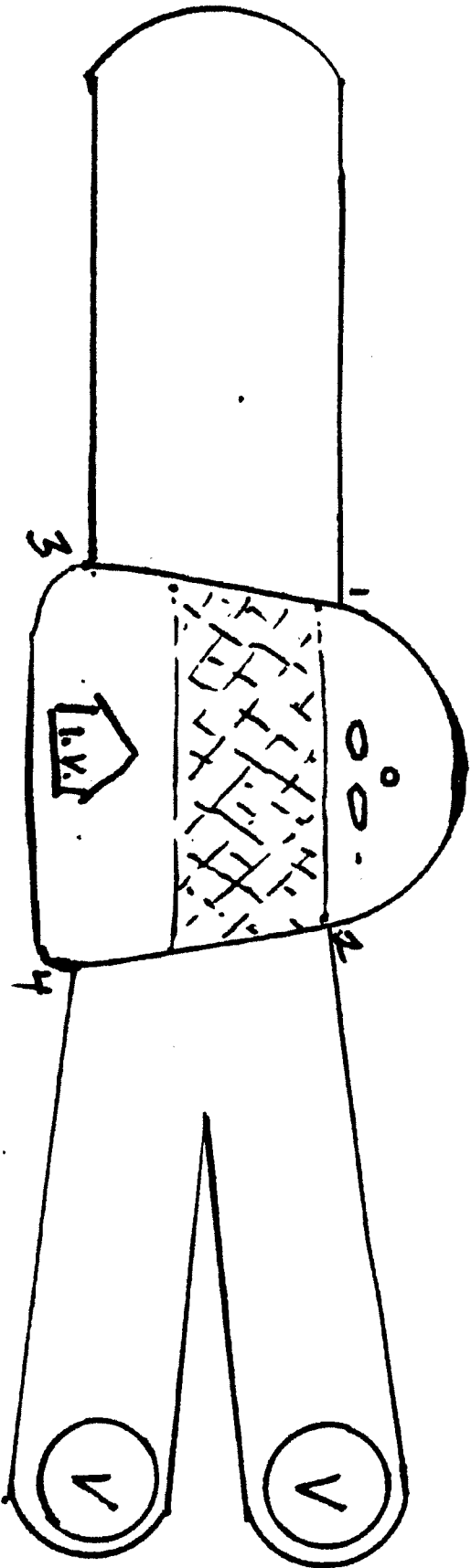
EDGES @

1, 2, 3, 4 OR ALL ALONG BOTH EDGES

I.V. HOUSE FULLY EXPOSED

1-8-2000

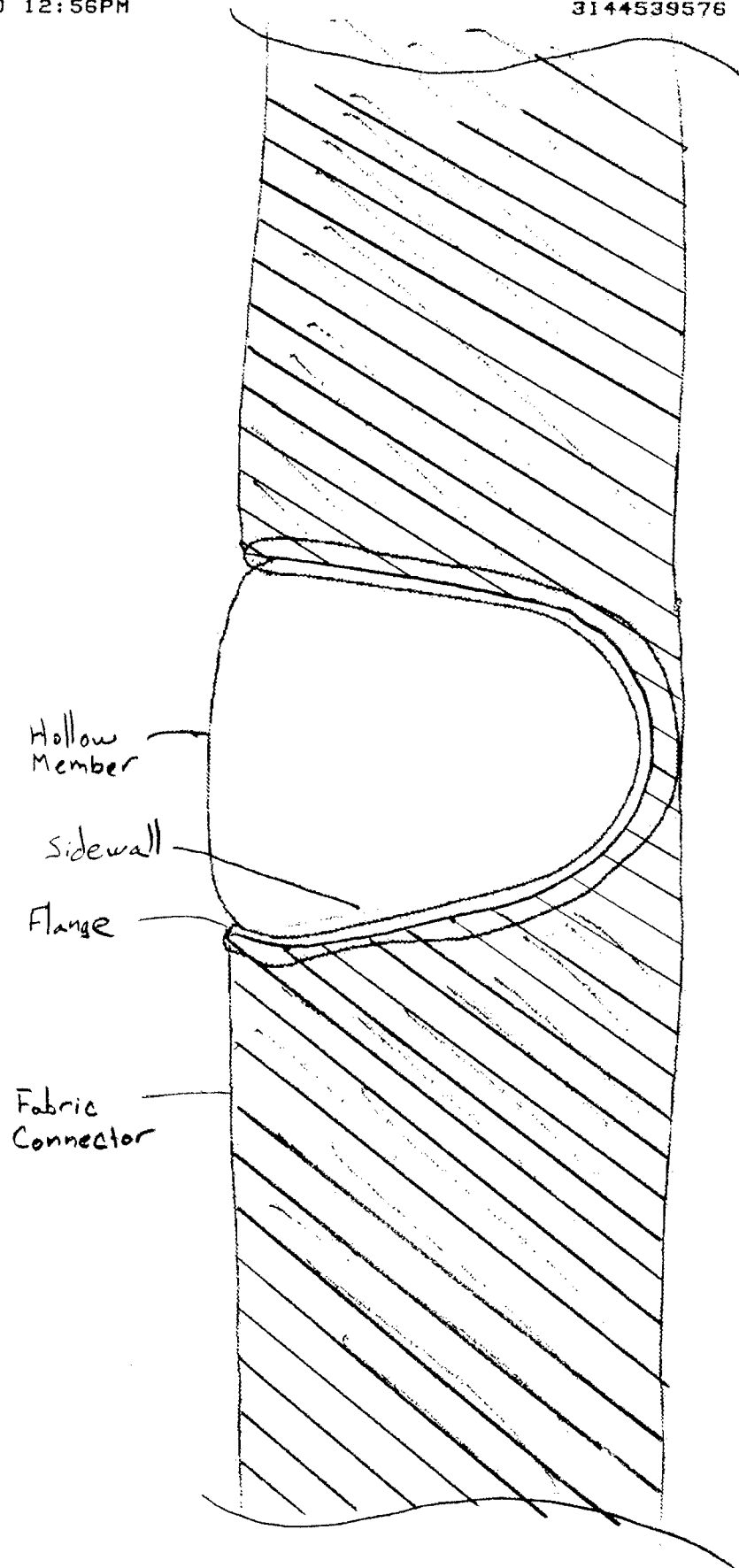
Fig. 8



LEFT HAND

TAPLESS  
WELDED TO  
EDGES @  
1, 2, 3, 4 OR ALL ALONG BOTH EDGES  
L.V. HOUSE FULLY EXPOSED

# EXHIBIT C



# EXHIBIT D

